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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/004,422

12/06/2001

Anuschirwan Peyman

02481.1773

8208

7590

01/09/2004

Finnegan, Henderson, Farabow,
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Washington, DC 20005-3315

EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,422

Applicant(s)

PEYMAN ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 8-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 8-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Amendment and response filed by applicants in Paper No. 11 dated Aug. 12, 2003 have been entered and considered carefully.

2. Claims 1-7 have been canceled. Claims 14-26 have been added and claims 8-13 are now dependent on claims 14-26.

The specification has been amended.

Initially, it is pointed out that it is NEW MATTER for the above amendments. Please note that formula III as now amended lacks antecedent basis in the description as originally filed. Especially the term "wherein B, together with D and the two carbons to which D is attached" encompassed limitation or subject matter which was not described within the four corner of the specification as originally filed. Please note that, D and the two carbon to which D is attached are all "saturated" bonds. Therefore, the NEWLY ADDED formula III wherein B, together with D and the two carbons to which D is attached is confusing as to what the structure is. Is it B is mono- or bicyclic aryl together with D which would be i.e. dihydroindolyl ring, or the whole ring is phenyl or???? In so far as the newly added formula III and the originally filed formula III is concerned, the newly described formula III is not identical to the originally filed description or within the scope of the originally filed description but contain additional rings i.e. tricyclic ring (B=bicyclic together with unsaturated -C-B-C-).

Based on the above explanation, if the B-D ring system as now amended will be drawn to only fused ring system, then, applicants have canceled all of the elected invention.

Applicants are advised to limit the claims to the elected invention (see page 2, office action Paper No.9 dated 04/18/03) which has been clearly delineated based on applicants' election.

3. The rejections of 1-6 are dropped in view of the cancellation of the claims.

4. Claims 8-26 as now amended are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Please note as it was explained supra in section 2, the newly amended fused ring system with “-C-D-C-” being saturated are not described in the specification as originally filed.

Removal of all new matter is required. In re Ressemussen 211 USPQ 325.

5. The amendment filed in Paper No. 11 to the specification is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure as it has been explained supra in section 2.

Applicant is required to cancel the new matter in the reply to this Office Action.

6. Claims 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The notation of “B” is confusing since the capital letter “B” in chemistry is normally referring to boron and heterocyclic rings can have boron as a ring element.

7. The rejections of claims 1-13 under 35 USC 103(a) over Beight ‘200 in view of Klein ‘339 or Klein ‘339 in view of Beight ‘200 are applicable to the now amended claims 8-26 and are maintained for reason of record.

Applicant's argument is that the limitation of Q and Q' being bond or oxygen and X being C₁₋₆ alkylene obviated the Beight reference since such linker was not included in the reference. This is erroneous, please note that such teaching is not only generically included in the description, specific examples such as col. 45-46 examples 32-33 explicitly showed the one of Q or Q' is “O”, the other is bond and X is methylene structure. The insertion of one methylene between the amido linker and the aminoimino substituted phenyl is taught by Klein ‘339 as delineated in the previous office action.

The erroneous typographical error in calling the Beight ‘200 reference Ackman ‘439 is hereby corrected. Please note that applicants are fully aware of the error since the Beight ‘200

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reference was clearly named in the rejection and was only referred to erroneously in the explanation.

8. The rejections of claims 9-11 under 35 USC 112 first paragraph for lacking descriptive support for the claimed scope is new applicable to claims 21-26 and is maintained for reason of record. Please note that anticoagulant can not treat all cardiovascular disorders, i.e. hypertension is a cardiovascular disorder which is not treatable by anticoagulants. The broad scope encompassing "any and all" prodrug for which descriptive and enabling support have not been found in the specification is still in claim 9 or its dependent claims.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

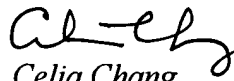
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

OACS/Chang
Jan. 6, 2003


Celia Chang
Primary Examiner
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